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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,202	01/26/2006	Andrew Timothy Boam	056258-5107	2377

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MORGAN LEWIS & BOCKIUS LLP
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WASHINGTON, DC 20004

EXAMINER

MCINTOSH III, TRAVISS C

ART UNIT	PAPER NUMBER
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1623

MAIL DATE	DELIVERY MODE
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11/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/539,202	Applicant(s) BOAM ET AL.	
	Examiner TRAVISS C. MCINTOSH III	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-14 is/are rejected.
- 7) ☒ Claim(s) 2 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The Amendment filed August 25, 2009 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claim 3 has been amended.

Claims 10-14 have been added.

Remarks drawn to rejections of Office Action mailed March 31, 2009 include:

102 rejections: which have been overcome by applicants amendments and have been withdrawn.

An action on the merits of claims 1-14 is contained herein below. The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3-4 and 10-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 includes the limitation of various “**substituted** or unsubstituted” groups. In the absence of the identity of moieties which are intended to be substituted, thus modifying an art

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recognized chemical core, described structurally or by chemical name, the identity of “substituted” would be difficult to ascertain. In the absence of said moieties, the claims containing the term “substituted” are not described sufficiently to distinctly point out that which applicant intends as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1 and 5-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO98/15591.

The claims of the instant application are drawn to methods of purifying oligonucleotide synthons comprising subjecting an organic solution comprising an oligonucleotide synthon and impurities to nanofiltration whereby the impurities pass through and the ratio of oligonucleotide

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synthons to impurities increases after nanofiltration. Dependent claims provide for various membrane types, and limits the various operation conditions.

The '581 patent discloses methods of purifying nucleotides, nucleosides, and nucleotide sugars by contacting a feed solution containing the nucleotide or related compound with a nanofiltration or reverse osmosis membrane under conditions such that the membrane retains the nucleotide or related compound while a majority of the contaminant passes through the membrane. On page 8 the '581 document discusses the membranes used and the use of membranes having a molecular weight cut-off which are less than the molecular weight of the compound being purified, such as using membranes with molecular weight cut-offs of less than about 200 Da. On page 13, the pressure, flow rate and temperature of the filtration process is discussed for optimizing the method. Page 21 discusses the various nucleotides which are intended to be purified by nanofiltration, such as various phosphate nucleotides as well as the deoxy forms and other nucleotides. The prior art is seen to teach methods of purifying nucleotides of various structures with nanofiltration whereby the compounds are retained in the solution and the impurities are passed through the membrane, thus increasing the ratio of compound to impurity level in the solution after filtration.

The '581 patent is silent to the use of an organic solution, however, it would have been obvious to one of ordinary skill in the art at the time of the invention to use an organic solution in the '581 patent. Applicants argue that the '581 patent does not set forth the oligonucleotide synthons as set forth in applicants claims, however, the examiner notes that claims 1 and 5-14 are broad enough to be encompassed by the compounds separated in the '581 patent. Likewise, applicants argue that the '581 patent uses aqueous solutions and not organic solutions. However,

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the examiner believes that it would have been obvious to use either an organic or aqueous solution with the '581 patent before them. While page 9 of the '581 patent does discuss various pH requirements, this is seen to be more drawn to selecting the charge of the membrane as it relates to the carbohydrates and impurities being separated. Likewise, because the '581 patent discusses various pH modifications, this does not delimit the teaching of the reference as a whole, as just because the instant claims are silent to the pH, does not render them nonobvious over art that does discuss pH variations in the process. A skilled artisan would have found it obvious to practice the methods of separation as set forth in the '581 patent using various solvents to obtain the methods instantly claimed.

Conclusion

Claim 2 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TRAVISS C. MCINTOSH III whose telephone number is (571)272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Traviss C McIntosh III/
Primary Examiner, Art Unit 1623
November 6, 2009